UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

BRAINTREE LABORATORIES, INC., Plaintiff, v. BRECKENRIDGE PHARMACEUTICAL, INC., Defendant.	)	Civil Action No. 12-cv-6851-AJN [rel. 14-cv-8147-AJN] ECF Case

DECLARATION OF MARK CLEVELAND, PH.D. IN SUPPORT OF BRAINTREE LABORATORIES INC.'S OPPOSITION TO DEFENDANT BRECKENRIDGE PHARMACEUTICAL, INC.'S MOTION FOR SUMMARY JUDGMENT OF NONINFRINGEMENT

I. INTRODUCTION

1. I am Dr. Mark Cleveland, a co-inventor of United States Patent No. 6,946,149 ("the '149 patent"). I am also Senior Vice President of Research and Development and Regulatory Affairs at Braintree Laboratories, Inc. ("Braintree").

2. I am submitting this Declaration in support of Braintree's Opposition to Defendant Breckenridge Pharmaceutical, Inc.'s ("Breckenridge") Motion for Summary Judgment of Noninfringement.

3. I am submitting this Declaration for three reasons: (1) to provide background information regarding Braintree and its history of development of colon preparation drugs; (2) to further explain the examples described in the '149 patent specification with respect to the volumes stated in the SUPREP® Bowel Prep Kit ("SUPREP") commercial product labeling; and (3) to explain, based on my personal experience, the effect of ingesting SUPREP before a

colonoscopy.

II. BRAINTREE LABORATORIES, INC.

4. Braintree is a small, privately-held pharmaceutical company based in Braintree, Massachusetts. Braintree is a pioneer in the development of gastrointestinal lavages for use before colonoscopy and related procedures, such as colon surgery. Since 1982 when it was founded, Braintree has developed a series of innovative laxative and colon cleansing products that are widely used today. These products include GoLYTELY®, NuLYTELY®, MiraLAX®, HalfLytely®, and SUPREP. Braintree currently has approximately 200 employees.

III. EXAMPLES IN '149 PATENT SPECIFICATION

5. As one of the co-inventors of the '149 patent, I was involved in designing the study that is described in the '149 patent specification.

6. When I first conceived of the idea that balanced solutions of sulfate salts could safely induce colonic purgation in preparation for colonoscopy, I contacted Dr. John Fordtran (also a co-inventor of the '149 patent), about working with him to design a study that would test this idea.

7. I wanted to design a colonoscopy preparation product that a patient would take in two administrations – similar to the Fleet's Phospho-soda product, but much safer for the patient. Fleet's Phospho-soda, which was a solution containing sodium phosphate, was a popular small-volume colonoscopy prep drug on the market at the time. Fleet's Phospho-soda was effective in cleansing the colon, but was associated with serious adverse health effects. It was later removed from the market due to significant safety problems.

8. We wanted our preparation to consist of a first administration taken the evening before the colonoscopy (to induce diarrheas or purgations), and the second administration taken the morning of the colonoscopy (to induce further purgations). Similar to Fleet's Phospho-soda, both purgation-inducing administrations would be required to adequately cleanse the colon prior to colonoscopy examination. The ultimate goal was a product that could safely replace Fleet's Phospho-soda in the marketplace. Therefore, similar volumes and methods of administration were studied.

9. Two-part administration is advantageous in producing a clean colon in preparation for a colonoscopy because: (1) it brings the last purgation close in time to the colonoscopy procedure, which minimizes any build-up of fecal material that may occur between the time of ingestion of the preparation and the time of the colonoscopy; and (2) it helps with patient compliance because the volume of solution that must be ingested by the patient at each administration is less than it would be if the entire preparation had to be ingested at once.

10. The "Examples" section of the '149 patent specification describes the experimental study in normal volunteers that Dr. Fordtran and I performed to develop a balanced solution of sulfate salts that could induce colonic purgation without causing the dangerous electrolyte abnormalities associated with Fleet's Phospho-soda preparation. The five experimental solutions that we tested were each 330 ml in total volume because that was the volume of the Fleet's Phospho-soda product used as the comparator product in the study. Each study subject ingested 165 ml of experimental solution or Fleet's Phospho-soda at 7 P.M. on day 1, and the other 165 ml at 5 A.M. on day 2.

11. As Braintree and I later worked further on the inventive composition described and claimed in the '149 patent, we had to make sure that the solution would not only be safe and effective, but also reasonably palatable. We found that when the solution was too concentrated and unflavored, it was not palatable. In addition, we found that when the solution was too concentrated, the salts would not always stay dissolved in the solution. Due to these two concerns that arose during early drug development, we increased the volume of the solution relative to the experimental solutions.

12. The SUPREP kit includes two bottles of solution. Each bottle contains 6 ounces, or about 180ml, of solution. We decided on this particular volume of solution for each bottle to minimize the risk that the salts in the solution would precipitate or separate out of the solution if the solution were to be stored at a low temperature. According to the approved product label, the patient is instructed to dilute the contents of each bottle of SUPREP solution with 10 ounces of water to a total of 16 ounces, or 473 ml, before ingesting the solution. This dilution of the SUPREP formula was necessary to permit acceptable flavoring of the sulfate salt solution.

IV. EFFECT OF INGESTING SUPREP

13. I have personal experience with ingesting SUPREP. I have taken SUPREP in preparation for a colonoscopy. Based on that personal knowledge, I have been asked to explain the physical effect of ingesting SUPREP.

14. When I took SUPREP as directed, I observed that about 45 minutes after ingesting the first diluted bottle of SUPREP, I had a copious watery diarrhea. Over the next several hours, I had a number of additional diarrhea events during which I evacuated copious amounts of watery diarrhea. During this time I drank the recommended amount of supplemental water to prevent

dehydration. Ingesting the second bottle of SUPREP the next morning caused the same effects. A few hours later I was ready for my colonoscopy.

I certify under penalty of perjury that the foregoing statements in this Declaration are true and accurate to the best of my knowledge.

Dated: July 15, 2015

Mark Cleveland, Ph.D.

CERTIFICATE OF SERVICE

I hereby certify that on July 20, 2015, a true and correct copy of the foregoing DECLARATION OF MARK CLEVELAND, PH.D. IN SUPPORT OF BRAINTREE LABORATORIES, INC.'S OPPOSITION TO DEFENDANT BRECKENRIDGE PHARMACEUTICAL, INC.'S MOTION FOR SUMMARY JUDGMENT OF NON-INFRINGEMENT was filed through the Court's Electronic Filing System (ECF), and was served electronically to the registered participants as identified on the Notice of Electronic Filing (NEF).

Dated: July 20, 2015 /s/ John J. Regan